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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,731	01/28/2005	Yoshihiko Kotake	0152-0702PUS1	8755
2292	7590	09/18/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			RAHMANI, NILOOFAR	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/522,731	Applicant(s) KOTAKE ET AL.	
	Examiner Niloofer Rahmani	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25,30-33,36-40 and 51-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 51-55 is/are rejected.
- 7) ☒ Claim(s) 23-25,30-33 and 36-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-25, 30-33, 36-40, 51-55 are pending and claims 26-29, 34-35, 41-50 are cancelled in the instant application.

2. ***Priority***

This application is a 371 of PCT/JP03/09753, filed on 07/31/2003, which claims the priority of JAPAN 2002224105, filed on 07/31/2002.

3. The rejection of claim 25 for "medication" under 112, second paragraph is withdrawn in view of applicant's amendment.

4. The rejection of claims 1-22 for "hydrates of those" under 112, first paragraph and second paragraph is maintained for reason of record. Applicants argue that changing the term "hydrate of those" to "hydrate thereof" would obviate the rejection. It is the examiner's position that hydrate is unpredictable because there are different hydrates. There are $\frac{1}{2}$ hydrate, 3 hydrates, or $\frac{3}{4}$ hydrate, etc. therefore, the specification lacks description of "hydrates".

5. The rejection of claims 51-53 for "6-deoxy 11107" under 112, second paragraph is maintained for reason of record. Applicants argue that the 6-deoxy 11107 compounds are well defined in the specification beginning at page 75, line 17 up to page 93. It is the examiner's position that the term "6-deoxy 11107" is undefined. What is 6-deoxy 11107? It is recommended to define it.

6. The rejection of claims 52, and 54-55 for "strain-A-1543(FERM BP-8442)" under 112, second paragraph is maintained for reason of record. Applicants argue that the term "strain-A-1543(FERM BP-8442)" is defined as : FERM BP-

8442, which is the international accession number of the microorganism. It is the examiner's position that the term "strain-A-1543(FERM BP-8442)" is undefined. It is recommended to define it.

7. The rejection of claim 53 for "biologically converting" under 112, second paragraph is maintained for reason of record. Applicants argue that the term "biologically converting" is defined as microbially converting 6-deoxy 11107B to 6-deoxy 11107 by culturing a microorganism capable of chemically converting 6-deoxy 11107B to 6-deoxy 11107, in a medium capable of chemically converting 6-deoxy 11107B. It is the examiner's position that the term "biologically converting" is not defined in the specification. Is it enzyme or another microorganisms? The term "biologically converting" is still unclear as to the Meets and Bounds of the claims. Correction is required.

8. The rejection of claim 51 under 112, first paragraph is maintained for reason of record. Applicants argue that specific conditions for the method of claim 51 are given in the specification. See pages 75-93 of the specification. Variations of the method of claim 51 would be well understood by one skill in the art. It is the examiner's position that the claim encompassed any and all conditions and the whole genus *Streptomyces* for producing a 6-deoxy 11107 compound from culturing a microorganism belonging to the genus *Streptomyces* for which insufficient description was found in the specification for all conditions and all for the genus.

9. The rejection of claim 51-55 under 112, first paragraph is maintained for reason of record. Applicants argue that as described on page 79, lines 10-20 species of the genus have been internationally deposited. It is the examiner's position that the international deposit rules is not sufficient to satisfy US practice. 37 CFR 1.803(d) indicates that once a depository is recognized as suitable for the purposes of this rule, or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Gazette of the Patent and Trademark Office. A current list (as of January, 1998) of IDAs recognized under the Budapest Treaty, with addresses, is included below. The mere fact that a deposit has been made in one of these depositories does not mean that the terms of the deposit meet either the requirements of the Budapest Treaty or the deposit regulations. Many of the depositories recognized under the Budapest Treaty have many different arrangements under which biological material may be stored.

37 CFR 1.808 requires that the deposit of biological material be made under two conditions:

- (A) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and
- (B) with one exception, that all restrictions imposed by the depositor on the

availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent.

The one exception that is permitted is specified in 37 CFR 1.808(b) which permits the depositor to contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent, meets any one or all of the three conditions specified in this paragraph. These conditions are:

- (A) the request is in writing or other tangible form and dated; and /or
- (B) the request contains the name and address of the requesting party and the accession number of the deposit; and /or
- (C) the request is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished.

It should be noted that this exception to the general rule that all restrictions will be removed must be strictly followed and that no variations of this explicit exception will be accepted as meeting the conditions of this section. Although this exception is consistent with the provisions in the Budapest Treaty and its implementing regulations (Rule 11.4), other conditions on accessibility are permitted under the Budapest Treaty as prescribed by national law.

Consequently, the mere indication that a deposit has been made under conditions prescribed by the Budapest Treaty would satisfy all conditions of these

regulations except the requirement that all restrictions on access be removed on grant of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

The specification at page 78-80 does not satisfy the Budapest Treaty and US required assertion of removal of all restrictions. As such, the deposit in the specification is insufficient for US Practice. MPEP 2402 specifically identifies the criteria necessary if the deposit was not made according to the Budapest Treaty.

Finally, it appears from the description at at least pages 78-80, that the macrolide structure can be produced by any *Streptomyces* sp. Therefore, I see no patentable distinction between the deposited strain and any random *Streptomyces* species. A mere deposit does not render a product distinct from other species and strains of *Streptomyces*.

10. *Claim Objections*

Claims 23-25, 30-33, 36-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

09/13 /2006

NL


D. MARGARET SEAMAN
PRIMARY EXAMINER
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